

ACC NEWS



President's Page: Cardiac Catheterization Laboratories: Hospital-Based, Freestanding or Mobile?

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In 1990, the majority of patients who undergo cardiac catheterization will have the procedure performed in a hospital-based catheterization laboratory. Most of these patients will be hospitalized for the procedure, but many will be outpatients. Thus, the era of outpatient cardiac catheterization is on us, and I believe it is here to stay. However, I also believe that one must clearly differentiate outpatient catheterization performed in a hospital facility with surgical backup from that performed in a freestanding or a mobile cardiac catheterization laboratory with no surgical backup. What follows is my own assessment of the situation as it stands in early 1990.

Background. In May 1985, the American College of Physicians issued a Clinical Efficacy Assessment Project (CEAP) position statement on ambulatory cardiac catheterization (1). It stated that for certain adult patients with stable coronary symptoms, full hospitalization for cardiac catheterization and angiography might not always be necessary. It appeared that these procedures could be safely performed in the outpatient setting of a hospital facility, assuming immediate access to cardiac surgery if necessary and accommodations for 4 to 6 h of postprocedural observation. The statement warned of the relatively high risk of the procedure for certain patients, such as the very young and the very old. Because survival rates in these groups of the young and old were lower than rates for the general population of hospitalized patients, hospital-based procedures were considered to be essential.

In December 1985, a joint statement on ambulatory cardiac catheterization was issued by the American College of Cardiology (ACC) and the American Heart Association (AHA) (2). Both organizations concurred with the recommendations of the American College of Physicians and

further outlined specific conditions under which patients should not ordinarily undergo outpatient cardiac catheterization. Their statement also reinforced the position that the presence of facilities for postcardiac catheterization observation was essential, in addition to assured availability of a hospital bed and access to emergency surgery if needed.

Interim developments. Since promulgation of these policies in 1985, several developments have occurred. First, there has been a proliferation of cardiac catheterization laboratories, with some 1,200 facilities nationwide now identified. Second, as the nation responds to cost-containment initiatives, some new types of laboratories are being presented as less costly than those in the traditional setting of a hospital.

The problem: insufficient data. In 1989, the Office of Health Technology Assessment with the assistance of the National Center for Health Services Research and Health Care Technology Assessment (3) analyzed the experiences (some published, some not) of several ambulatory and freestanding cardiac catheterization laboratories. The authors of the analysis summarized a previous literature review that had revealed little consensus within the cardiovascular community on the use of freestanding catheterization laboratories. Furthermore, in that review, ambulatory and freestanding cardiac catheterization laboratory data were inappropriately compared; the outpatient hospital setting is quite different from the freestanding setting, making these two environments not comparable.

In 1986, Kathleen L. Kahn, MD (4) of the Rand Corporation had reviewed available reports and expressed her concerns about adequate evaluation of outpatient cardiac catheterization. Her views were summarized in the Office of Health Technology Assessment report (3) as follows: "... the lack of data regarding the types and severity of pathology in patients studied in the different ambulatory settings makes it difficult to assure comparability of the populations. Therefore, comparison of mortality and mor-

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idity rates from hospital and freestanding settings would not provide an accurate picture of the importance of the cardiac catheterization venue to the outcome of cardiac catheterization". Despite these and other valid concerns, the Office of Health Technology Assessment concluded that patients in the freestanding setting enjoy a lower rate of complications.

The Office of Health Technology Assessment report (3) also cites the results of one study of interhospital transport of patients receiving intraaortic balloon support as indicative that this type of highly technical transport is feasible for patients who have complications after cardiac catheterization in the freestanding setting. Independent review of this article indicates that the Office of Health Technology Assessment has drawn a broader conclusion from this information than the original research suggests. The single institution studied had an active cardiac catheterization laboratory and a highly trained group of nursing, medical and paramedical personnel. The requisite ambulance support is specific and technical. One must ask the very important question: Can the availability of these support services be assured for each freestanding facility?

The authors of the Office of Health Technology Assessment report (3) readily acknowledge that the National Institutes of Health, The American Heart Association, the American College of Physicians, the American Society of Anesthesiologists and the American College of Cardiology do not support cardiac catheterization in the freestanding setting. The only organization cited in their report that does support this setting is the Association for Ambulatory Cardiac Catheterization.

More recently the California Department of Health undertook a demonstration project with the assistance of technical advisory committees to evaluate the safety and efficacy of freestanding and mobile cardiac catheterization laboratories. In August 1989 it was reported at a public hearing that inadequate data had been gathered to assess the concept of such laboratories and that the demonstration project should continue.

Cardiologists face the issue of proper referral and treatment for their patients when cardiac catheterization is indicated. Because there are few data on the experience of patients in alternative settings, it is difficult to provide a rational assessment of the specific instances when ambulatory catheterization in a freestanding laboratory is safe and efficacious and when it is not.

Another concern is the lack of quality control of the performance of freestanding or mobile cardiac catheterization laboratories. The Joint Commission on Accreditation of Health Care Organizations has developed criteria to be used to establish safety guidelines in the freestanding setting. However, only a small fraction of the existing laboratories have met the criteria, and the issues of ongoing supervision and review are not addressed.

Concerns of cardiologists. The ACC and the AHA want to assist federal agencies in carefully and adequately evaluating the safety and efficacy of freestanding facilities for cardiac catheterization and angiography. Toward that goal, the two organizations will soon undertake a survey of members and nonmembers to estimate the extent of cardiac catheterization procedures being performed and to learn more about the types of settings in which they are being performed. The survey will also seek to measure the attitudes and opinions of cardiologists about the safety and efficacy of performing the procedure in outpatient settings (hospital-based, freestanding and mobile). Results of the survey will be analyzed by the ACC/AHA Task Force on Cardiac Catheterization, which was formed to reconsider this issue. The recommendations of the Task Force are expected later this year.

Summary. As I recently wrote in an editorial in *Clinical Cardiology*, I believe that, although economic issues are of great concern, the safety of the patient has to come first (5). Pink et al. (6) have indicated that hospital facilities or the lack of hospital facilities and nursing staff will often dictate the necessity for performing procedures on an outpatient basis. However outpatient cardiac catheterization in the hospital setting is not the same as outpatient cardiac catheterization in a freestanding or mobile facility. Because a complication rate exists, I strongly believe that cardiac catheterization and angiography should be performed in a facility where surgical support is immediately available. The performance of special procedures (transseptal left heart catheterization and coronary angioplasty, for example) in a freestanding ambulatory setting is of particular concern.

However, let me state again that I believe that outpatient cardiac catheterization is here to stay. A major reason is the increasing need for repeated cardiac catheterization in several groups of patients with cardiac disease, including patients with a heart transplant, some patients with arrhythmia and patients undergoing coronary recanalization procedures, perhaps even patients undergoing valvuloplasty.

The lack of general guidelines on the characteristics of laboratories that can deliver optimal care and the lack of definition of patients suitable for cardiac catheterization in the various settings plus the inability to assure quality in freestanding or mobile outpatient catheterization settings leaves me to question their very existence. For these reasons, I believe it is prudent to proceed slowly and to not rush into the development of freestanding or mobile cardiac catheterization laboratories until adequate data are available to document their safety and efficacy.

Finally, I emphasize that the cardiologist performing catheterization who is contemplating outpatient procedures, whether in the hospital or in a freestanding or mobile unit, has the responsibility to decide which patients are at low risk and can satisfactorily undergo outpatient catheterization. The casual acceptance of patients for outpatient catheterization, who have not been adequately evaluated either by the

cardiologist performing the procedure or by physicians known to the cardiologist, is a risky business.

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